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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
GEORGE, KONATA M	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,836	JORDAN, FREDERICK L.	
	Examiner	Art Unit	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-35 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-35 are pending in this application.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on June 25, 2004 and December 23, 2004 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 22 and 23 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant in claims 22 and 23 claim a method of treating or preventing cancer and Alzheimer' disease by identifying a subject in need of a COX enzyme inhibitor and administering to said subject a transdermal delivery system according to claim 20 and 21 respectively. The specification does not enable one skilled in the art to use the composition as claimed. Page 4, lines 7-11 disclose "Additional methods of the

invention include approaches to treat cancer and Alzheimer's disease..." also, page 26, lines 30-31 and page 27, lines 10-23 talk about treating cancer and Alzheimer's disease. However, there is no disclosure with respect to examples or studies that show treating cancer and Alzheimer's disease with the composition as claimed.

3. Claims 1-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 19 also recites "a therapeutically effective amount of a delivery agent". Applicant's use of the term "delivery agent" is repugnant to the normal use of the term in that art as well as all the delivery agents discussed in the specification are discussed as actives, for example the capsaicin and NSAIDs are for the treatment of pain and the collagen delivery agents as a cosmetic active. On page 6 of the specification the applicant defines "delivery agent" as "a molecule of mixture of molecules (e.g., a pharmaceutical or cosmetic agent) that are delivered to the body...can include, for example, a protein, a sugar, a nucleic acid, a chemical or a lipid...glycoprotein's, enzymes, genes, drugs and ceramides." It would be more accurately described as the delivered agent.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4, 5, 18, 19, 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite and should be rejected under 35 U.S.C. 112, 2nd paragraph as they recite an "ethoxylated lipid selected from the group consisting of castor oil, jojoba oil, corn oil and emu oil". From the specification it is clear that the applicant's intent is to claim ethoxylated caster oil, ethoxylated jojoba oil, etc... but that is not what the claim actually says. This limitation, as written, would be reasonably interpreted as meaning caster oil, etc... are ethoxylated lipids.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-4, 6, 7-15, 18, 20-24 and 31-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 7, 18, 24-32, 49, 55, 56, 65-68, 70-72 of copending Application No. 10/856,567. Although the conflicting claims are not identical, they are not patentably distinct from each other because both copending applications are directed towards a transdermal delivery system comprising an ethoxylated oil and a delivery agent. The difference between the two is that the instant application '836, the ethoxylated oil does not have to be mixed with the delivery agent whereas in the '567 application the delivery agent is mixed with the ethoxylated oil.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-4, 6, 7-15, 18, 20-24 and 31-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-14, 17-22 and 25-31 of U.S. Patent No. 6,759,056 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the pending application and the patent are directed towards a transdermal delivery system comprising an ethoxylated oil and a delivery agent. The difference between the two is that the instant application '836, the ethoxylated oil does not have to be mixed with the delivery agent whereas in the '056 application the delivery agent is mixed with the ethoxylated oil and contains an alcohol and an aqueous adjuvant. The pending

application system does not limit the composition to what is claimed and therefore can also contain an alcohol and an aqueous adjuvant.

7. Claims 1-4, 6, 7-15, 18, 20-24 and 31-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 9 and 17-23 of U.S. Patent No. 6,946,144 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the pending application and the patent are directed towards a transdermal delivery system comprising an ethoxylated oil and a delivery agent. The difference between the two is that the instant application '836, the ethoxylated oil does not have to be mixed with the delivery agent whereas in the '144 application the delivery agent is mixed with the ethoxylated oil and contains an alcohol and an aqueous adjuvant. The pending application system does not limit the composition to what is claimed and therefore can also contain an alcohol and an aqueous adjuvant.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-7 and 15-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Toppo (US 5,318,960).

Toppo discloses a system for transdermal delivery of pain relieving substances. The pain relieving composition comprises a pain relieving substance, an oil surfactant, a co-solubilizer and water (col. 2, lines 66-67). The pain relieving substance may be any one or more medicament including NSAIDs (col. 3, lines 33-65), the oil surfactant can include a polyethoxylated castor oil (col. 4, lines 2-3) and the co-solubilizer can by any alcohol except methanol (col. 4, lines 16-18).

Conclusion

9. Claims 1-35 are rejected.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8000 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George

Alton N. Pryor
Primary Examiner
A.U. 1616